

## Attachment 12

K970734

## 510(k) Summary

## Siregraph T.O.P. 33 and Siregraph T.O.P. 40

Submitted by:

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

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2. **Device Name and Classification:**

Trade Name:	Siregraph T.O.P. 33 and Siregraph T.O.P. 40 Universal Fluoroscopic X-ray Systems
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Device Code:	90JAA

3. **Intended Use:**

The Siregraph T.O.P. 33 and T.O.P. 40 Universal Fluoroscopic X-ray Systems are devices intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. Both systems have medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract, lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

4. **Substantial Equivalence:**

The Siregraph T.O.P. 33 and 40 are substantially equivalent to the following devices in commercial distribution:

# SIEMENS

- Siregraph D3 and D340, K860913  
Siemens Medical Systems, Inc.
- Siregraph CF, K960266  
Siemens Medical Systems, Inc.


5. **Device Description:**

Siregraph T.O.P. is a universal fluoroscopic X-ray diagnostic system with an overtable X-ray tube assembly. Two versions are available: Siregraph T.O.P. 33 for use with an undertable spot film device, and Siregraph T.O.P. 40 for use in Digital Fluoro Radiography (DFR) with an undertable Image Intensifier (I.I.). Both systems are operated either via table side control or the remote control console.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**

Siregraph T.O.P. has the same technological characteristics as the predicate Siregraph D3/D340. Both systems are remote fluoroscopic X-ray diagnostic systems with an overtable X-ray tube assembly. Like Siregraph D3 and D340, Siregraph T.O.P. consists of the basic system (patient support table), and standard system components: X-ray generator, X-ray tube, Image Intensifier, TV system, digital imaging system, monitors, optional Bucky wall stand and optional ceiling-mounted support for second X-ray tube. The differences between Siregraph D3/D340 and Siregraph T.O.P. are:

- The Siregraph T.O.P. basic system is redesigned for better ergonomics.
- The communication network among system components (e.g., generator, tube, etc.) has been updated. The XCS communication system is employed.
- Siregraph T.O.P. are configured with the latest commercially available system components.

  
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